

# The Artificial Heart: Total Replacement

By MICHAEL E. DeBAKEY

THE DEVELOPMENT OF A MECHANICAL PUMP to assist or replace the heart has engaged the interest of investigators for more than a decade. Our early interest toward this objective indicated the need for close collaboration of biologic and physical scientists. Accordingly, in 1963, the Biomedical Engineering Laboratories of Rice University joined our Surgical Research Laboratory at Baylor in this endeavor. Our initial efforts were directed toward total cardiac replacement, but it soon became apparent that the number of problems associated with this objective would require long-term investigation, along with the development of new knowledge. For this reason and because many patients need only temporary cardiac support during the critical recuperative period after cardiac damage, we turned our attention toward the development of a pump for support of the failing left ventricle, which seemed to be a goal that might be more readily achieved at that time, and it appeared that investigations along these lines might provide a better understanding of the mechanical and physiologic problems involved in the development of a biventricular pump.

Intensive investigations toward this objective over a period of several years resulted in the development of a left ventricular bypass pump.<sup>1</sup> This consisted essentially of a gas-energized pump of hemispherical design, made of impervious, Dacron-reinforced silastic with a molded diaphragm

separating the gas chamber from the blood chamber. Prosthetic ball valves are used at the inlet and outlet of the blood chamber to provide for unidirectional flow. Pressurized carbon dioxide pulsed into the gas chamber collapses the blood chamber to empty it. The external energizing and controlling system consists of Teflon bellows driven by an electric motor which, in turn, is controlled by phase variable firing of silicon-controlled rectifiers and a dynamic braking circuit. The pump may be controlled manually or by an electrocardiographic triggering mechanism.

The pump's inlet connecting tube, which lies outside the body, is inserted through an intercostal incision and attached to the left atrium by end-to-side anastomosis. The outlet tube of the pump is attached, by similar anastomosis, to a systemic artery such as the axillary artery. Removal of the pump when no longer needed consists simply in dividing the connecting tubes just beneath the skin, with the patient under local anesthesia, oversewing the proximal ends, and suturing the overlying skin.

One of the most important elements of the pump is the Dacron velour lining. It has long been recognized that one of the most critical problems to be solved in the development of an artificial heart is the blood interface or contact surface of the blood. When blood moves from its normal habitat within the heart and blood vessels and flows over a foreign surface of any kind, it undergoes abnormal changes that become progressively more severe the longer this contact continues. Our previous experience with the successful development of arterial prosthesis with the use of Dacron led us to investigate its application as a lining in a mechanical blood pump. From

---

*From the Department of Surgery, Baylor College of Medicine, and the Cardiovascular Research and Training Center, The Methodist Hospital, Houston, Texas.*

*Supported in part by USPHS Grants HE-05435 and HE-09251, National Heart and Lung Institute, Bethesda, Md.*

these investigations, a Dacron velour lining was developed which provided a means of enmeshing the fibrinous material deposited by the blood in the loops of the velour surface to create a new surface in which the fibrinous elements adhere firmly to the Dacron velour fabric. Experimental studies showed that this type of lining provided a glistening, firmly adherent, fibrinous surface intimately attached to the Dacron velour lining, which was compatible with blood and which would not fragment or produce embolization with repeated to-and-fro motion of the diaphragm of the pump, even after 6 wk of continuous pumping.

Extensive laboratory testing over several years in a large series of animals demonstrated the safety and effectiveness of the pump.<sup>1</sup> On this basis, clinical investigations were begun in 1966 in a small series of carefully selected patients critically ill with valvular heart disease characterized by extremely low cardiac output, high left ventricular end-diastolic pressure, and very high left atrial and pulmonary arterial pressure. The left ventricular bypass pump was readied for use in the operating room in case it was found, after completion of the valve replacement procedure, that the heart was unable to sustain an adequate cardiac output without support of the artificial heart-lung machine. In some patients in whom the left ventricular bypass pump was readied for use, prolonged assistance for 1-2 hr with the heart-lung machine was adequate to permit resumption of adequate cardiac function and discontinuance of cardiopulmonary bypass completely. Under these circumstances, the left ventricular bypass pump was not used. In other patients, however, even after such prolonged assistance with the heart-lung machine, it was not possible to discontinue cardiopulmonary bypass, and more prolonged assistance was required. It was under these circumstances that the left ventricular bypass was used.

In the first two patients in whom the pump was used and in whom it proved effective in providing cardiac assistance, it was attached as a paracorporeal pump. Certain technical problems in its application, however, led to modification in its clinical application so that the pump is now placed entirely external to the chest wall. In the six patients in whom it was subsequently used in this manner, it proved to be highly effective in providing cardiac assistance over a period of several days to almost 2 wk. Pump flows ranged from 1½ to 3 liters/min without significant damage to blood, as evidenced by maintenance of plasma hemoglobin levels within acceptable limits. In one patient, for example, the plasma hemoglobin level was progressively reduced during the 10-day period when the pump was used from 33.6 mg/100 ml on the first day after operation to 4.8 mg/100 ml on the tenth day.

The effectiveness of the pump as an assistive device for cardiac function was demonstrated on numerous occasions during the postoperative course of these patients.<sup>2</sup> In one patient, for example, acute pulmonary edema occurred suddenly on the seventh postoperative day, when the left atrial pressure rose sharply to 45 mm Hg. An increase in outflow of the pump from 450 to 1400 ml/min caused left atrial pressure to fall promptly to 15 mm Hg, with disappearance of all signs of acute pulmonary edema within a matter of minutes. On another occasion, on the fourth day after operation it was noted that the systemic blood pressure continued to fall, while the left atrial pressure was rising, and that the urinary output had decreased to about 10 ml per half hour. Administration of diuretics failed to produce any response over a 5-hr period. The output of the left ventricular bypass pump was then increased from 400 to 800 ml/min, with an immediate drop in left atrial pressure and severe diuresis. Two of these patients were long-term survivors, and one remains well

and normally active about 5 yr after mitral and aortic valvular replacement.

After the first human cardiac transplantation was performed in late 1967, the need for development of an artificial heart, at least for temporary use, became more urgent.<sup>5</sup> This development, along with the successful demonstration of the clinical effectiveness of the left ventricular bypass pump, prompted us to resume our earlier research efforts in development of a pump for total cardiac replacement. The design for such a pump was completed in September 1968 as a direct outgrowth of the single-ventricle pump.<sup>6</sup>

### *Biventricular Artificial Heart Pump Unit*

The right and left ventricles of this pneumatically controlled orthotopic cardiac prosthesis, a diaphragm design, were made of impervious Dacron embedded in silastic (Dow-Corning Corp., Midland, Mich.). The two separate units each contained a valve between the atrioventricular chamber and the outflow chamber. Connected to each ventricle and brought out through an intercostal space was Dacron-covered silastic tubing that provided a pathway for pulsing the diaphragm by attachment to the two external pneumatic power units. A separate pressure line attached to the left atrial chamber permitted continuous monitoring of atrial pressures. The pump chamber, as well as inflow and outflow tracts, were lined with special Dacron reticular fabric to enhance formation of an autologous blood interface. The thin, flexible, cuff-shaped inflow tracts were fabricated of impervious Dacron felt and silastic adhesive. Attached to the infundibular-shaped outflow tracts for suturing to the pulmonary artery and ascending aorta were woven DeBakey arterial grafts. The body, dome, and diaphragm are individual components of this pump unit and were constructed separately. The diaphragm was made of silastic pressed into reticular Dacron, with a total thickness of about 0.045 in. It was

molded in a systolic position and attached to the pump by a modified "O" ring molded into the diaphragm rim.

### *Power Unit*

Silastic tubing, 5 mm in internal diameter and covered with special Dacron, connects the external energizing unit to the intrapericardial pumps. The ventricle power unit has two major subsystems, the pneumatic pressure sources, and the monitor-control unit. The two pneumatic power units, each with a motor-driven pump, generate the pressure and vacuum needed to pulse the prosthesis. Carbon dioxide was the transmitting gas. The pulse unit controlled pulse rate and systolic duration and provided for synchronization of the two pneumatic sources. A display oscilloscope, four pressure preamplifiers, and the pulse unit comprised the monitor-control unit.

### *Experiments*

This model was implanted into seven calves by an operative technique similar to that used for allotransplantation of the human heart. The first four calves died on the operating table because of technical difficulties. Anastomosing the atrial flange, with leakage of blood and air, and consequent air embolism, proved to be the most important problem. After modification of the design to permit better attachment of the device, technical application of the pump in the next three calves was satisfactory, but adequate viability of vital organs was not maintained in any of them, although one survived 12½ hr.

Homograft, heterograft, and prosthetic graft valves were tried, but none proved entirely satisfactory, and the diaphragm was found to be unsatisfactory in some of the calves. In a few calves, pulse wave forms, arterial pressure levels, and left and right atrial pressures were satisfactory for brief periods, but it was not possible to assess circulation and peripheral perfusion or the potential traumatic effect of the

pump on the blood. On the basis of these observations, we concluded that the bi-ventricular pump was feasible but that it was not ready for human implantation because it would not provide adequate perfusion to maintain viability of vital organs.

#### PRESENT STATUS AND UNRESOLVED PROBLEMS

At this stage in the development of an artificial heart, several serious problems remain unresolved: an implantable power system; an antithrombogenic biomaterial for lining the pump; and fluid flow difficulties within the pump, causing irregular fibrous deposition and thrombosis. During the past several months we have tried to resolve some of the technical problems encountered in experimental use of our previous models. Damage has occurred from the heart-lung machine before implantation of the artificial heart, and the pump has been incapable of delivering sufficient cardiac output as a result of restricted venous inflow and low circulatory blood volume. Additional problems have included high incidence of air embolism, technical breakdown of the pump or its driving mechanism, and surgical complications during insertion or suturing, and various complications, due to the peculiarities of the experimental animals. Because the large size of the pump was a source of difficulties, the model was redesigned so that it would fit into the cavity of the natural calf heart. The valves were also redesigned to conform to the new ventricular configuration and each

ventricle was made capable of pumping 10 liters/min. A modified version of the Hufnagel connecting system for the aortic and pulmonary anastomoses provided a refinement that reduced the operating time and therefore the hematologic complications. To eliminate trial compression, the atrial cuff was cut on a bias.

This new design is now undergoing mock circulatory loop testing as a preliminary to implantation in calves. The problem of biocompatibility persists, but its importance will remain obscure until animals on total orthotopic cardiac replacement can be kept alive long enough to assess this complication. Animals that have survived as long as 10 days have died of bacterial infections rather than incompatible biologic interfaces.

In 1967, Geddes et al.<sup>7</sup> described a method they had developed to support the total circulation in the closed-chest animal with ventricular fibrillation. The technique involved combining low-pressure withdrawal from the left ventricle by means of carotid catheterization, with high-pressure reinfusion into the femoral and carotid arteries. In preliminary experiments in dogs, total circulatory support was maintained for 1–13 hr, after which the ventricles were defibrillated and normal blood pressure was reestablished. This technique had advantages over previous techniques of supporting the circulation in the failing heart because it offered total circulatory support and did not require a thoracotomy.

#### REFERENCES

1. DeBakey, M. E., Liotta, D., and Hall, C. W.: Left-heart bypass using an implantable blood pump. In *Mechanical Devices to Assist the Failing Heart*, Chapter 18. Washington, D. C., National Academy of Sciences, National Research Council, 1966, p. 223.
2. DeBakey, M. E.: Indirizzi attuali nel programma del cuore artificiale. *Gazzetta Sanitaria* 39: 313, 1968.
3. DeBakey, M. E.: Ricerche per un cuore artificiale. In *Scienze e Tecnica* 69. Arnoldo Mondadori Editore, 1968, Section II, Health: Social Aspects and Progress in Therapy, Part 9, p. 153.
4. —: Left ventricular bypass pump for cardiac assistance. *Amer. J. Cardiovasc.* 27:3, 1971.
5. —: Editorial: Human cardiac transplantation. *J. Thorac. Cardiovasc. Surg.* 55:447, 1968.
6. —, Hall, C. W., Hellums, J. D., O'Bannon, W., Bourland, H., Feldman, L., Wieting, D., Calvin, S., Smith, P., and Anderson, S.: Orthotopic cardiac prosthesis: preliminary experiments in animals with biventricular artificial heart. *Cardiovasc. Res. Cent. Bull.* 7:127, 1969.
7. Geddes, L. A., Schuhmann, R. E., Hoff, H. E., Moore, A. G., and Peters, J. L.: Total maintenance of circulation in the closed-chest animal with ventricular fibrillation. *Cardiovasc. Res. Center Bull.* 6:33, 1967.